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Veterinary Medicines and Product Data Management

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 34 referral for Synulox Lactating Cow and associated names

International non-proprietary name (inn): amoxicillin trihydrate, potassium clavulanate, prednisolone

Background information

Amoxicillin is a broad spectrum bactericidal β-lactam antibiotic. Clavulanic acid inactivates β-lactamases. This combination is effective against β-lactamase producing organisms. Prednisolone is an anti-inflammatory corticosteroid. Synulox Lactating Cow and associated names is a 3 g pale cream/buff coloured oily suspension presented in disposable intramammary syringes containing 200 mg amoxicillin as amoxicillin trihydrate, 50 mg clavulanic acid as potassium clavulanate and 10 mg prednisolone. The product is intended for the treatment of bovine clinical mastitis in lactating cows.

Due to the divergent national decisions taken by Member States concerning the authorisation of Synulox Lactating Cow and associated names and differences between the summary of product characteristics (SPC) of the product as authorised in the Member States, the issue was referred on 26 March 2010 by Belgium and Denmark to the CVMP under Article 34(1) of Directive 2001/82/EC.

The reason for divergent national decisions regarding the authorisation of the products was mainly the justification of the combination of amoxicillin/clavulanic acid/prednisolone for the treatment of bovine mastitis. The main sections of disharmony of the existing SPCs related to indications, posology and withdrawal periods.

The referral procedure started on 14 April 2010. The Committee appointed Dr Bruno Urbain as rapporteur and Mrs Ruth Kearsley as co-rapporteur. Further to the resignation of Mrs Ruth Kearsley as CVMP member, Ms Helen Jukes was appointed to replace her and took over the co-rapporteurship. Written explanations were provided by the marketing authorisation holders on 18 August 2010 and 8 February 2011. Oral explanations were given on 4 May 2011.

Based on the rapporteurs' assessment of the currently available data, the CVMP considered that the benefit/risk profile for Synulox Lactating Cow and associated names remains positive subject to

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variation of the marketing authorisations in accordance with the summary of product characteristics, and therefore adopted a positive opinion on 7 June 2011.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended summary of product characteristics in Annex III.

The final opinion was converted into a Decision by the European Commission on 20 October 2011.